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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,201	08/22/2000	Gerardo V. Noriega	19635-000210US	1112

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EXAMINER

NGUYEN, VI X

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/26/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/644,201

Applicant(s)

NORIEGA ET AL. *en*

Examiner

Victor X Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-25,27-39,67-70 and 72-80 is/are pending in the application.
- 4a) Of the above claim(s) 26,40-66 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25,27-39,67-70 and 72-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Reconsideration of Cited Arts**

1. In the Final Office Action, Claims 14, 21, 24 were indicated as allowable if rewritten in independent form and claims 31-39 were indicated as allowed. The claims were amended accordingly. However, in light of a new interpretation of the Adam and the Passafaro references, the indicated allowable subject matter is now rejected.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-19, 20-25, 27-36, 38-39, 67-69, 71-74 and 76-80 are rejected under 35 U.S.C. 102 (e) as being anticipated by Adams (U.S. 6,312,438).

As to claims 1 and 80, Adams disclose in figs 1-3 and col. 3, lines 15-67, an assembly having all the limitation as recited in the above listed claim, including: a guide wire (item 12 is a hollow, flexible tube for insertion into a body cavity or vessel to allow the passage or distend a passageway); a drive shaft (34), wherein said drive shaft (34) includes a distal tip (36) which can create a path through stenotic material.

As to claims 3-8, 21-23, 68-69 and 72, wherein the assembly has a torqueability and pushability to be advanced through a body lumen; and wherein the assembly further includes a motor (labeled in col. 6, lines 55-64) coupled to the drive shaft. The drive shaft (34) can be

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manually rotated. The distal tip (36) is flattened and twisted (50, fig. 2). The distal tip (36) has a width which is larger than the width of the drive shaft; and wherein the hollow guide wire (12) is steerable.

As to claims 9-12, wherein a housing (16) coupled to the proximal end of the hollow guide wire; wherein said housing (16) including an actuator (labeled in col. 10, lines 1-4), wherein the drive shaft (34) defines a longitudinal axis and the actuator moves the drive shaft along the longitudinal axis; and wherein the housing (16) includes an aspiration port (74) coupled to the hollow guide wire.

As to claims 13-15, wherein the guide wire (12) is in stationary position while the drive shaft (34) facilitates transportation of a removed occlusive material. The distal tip of the drive shaft is radio-opaque (labeled in col. 10, lines 53-65).

As to claims 16-19, wherein a support system having a distal end, wherein the hollow guide wire (12) passes through the support system in order to allow the distal tip is positioned beyond the distal end of the hollow guide wire and the support system; wherein the support system includes placing means disposed near distal end of the support system within the body lumen; and wherein the hollow guide wire is through a vasculature and the drive shaft (34) defines a longitudinal axis, wherein the distal tip is deflected off the longitudinal axis.

As to claims 20, 31 and 67, Adams disclose in figs 1-3 and col. 3, lines 15-67, an assembly having all the limitation as recited in the above listed claims, including: a hollow guide wire (12); a rotating mechanism coupled to the drive shaft (34); wherein an actuator (labeled in col. 10, lines 1-4) coupled to the drive shaft (34); and wherein the activation of the actuator advances the rotatable drive shaft (34) from a retracted position to an extended position; wherein

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said drive shaft (34) including a flattened and twisted distal tip (36, fig. 2) can be rotated and created a path through stenotic material.

As to claims 24-25, wherein the distal tip portion includes a spiral with a blunt tip (fig. 2); and wherein the hollow guide wire (12) has a torqueability and pushability to be advanced through a body lumen.

As to claims 27-30, wherein the rotating mechanism and actuator (labeled in col. 10, lines 1-4) are coupled together such that the drive shaft (34) is rotated and advanced simultaneously; and wherein the hollow guide wire (12) is configured to aspirate fluids and debris from stenosis.

As to claims 73-74, wherein the kit further a support system is sized to receive the hollow guide wire (12) and position the distal end of the guide wire is adjacent the occlusion; and wherein the support system includes an atherectomy catheter.

As to claims 76-79, wherein a motor can be coupled to the rotatable drive shaft (34); and wherein the housing (16) is coupled to the hollow guide wire (12) through a luer (35, fig. 1).

Claims 1, 20, 31, 67 and 80 are rejected under 35 U.S.C. 102 (e) as being anticipated by Passafaro et al (U.S. 6,156,046).

As to claims 1, 20, 31, 67 and 80, Passafaro et al disclose in figs 1, 1a, 2, 3, abstract and col. 11, lines 7-67, an assembly having all the limitation as recited in the above listed claims, including: a hollow guide wire (32); a rotating mechanism coupled to the drive shaft (52); wherein an actuator (42) coupled to the drive shaft (52); and wherein the activation of the actuator advances the rotatable drive shaft (52) from a retracted position to an extended position;

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wherein said drive shaft (52) including a flattened and twisted distal tip (96, fig.3) can be rotated and created a path through stenotic material.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 37 and 70 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Adams (U.S.6,312,438).

As to claims 2, 37 and 70, Adams discloses substantially limitations as recited in the claims, except for the guide wire has a diameter between approximately 0.009 inches and 0.035 inches. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the guide wire has a diameter between approximately 0.009 inches and 0.035 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 75 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Adams (U.S.6,312,438) in view of Noriega (U.S. 6,059,767).

As to claim 75, Adams teaches all aspect of the claimed invention except including a second guide wire. Noriega teaches a second guide wire (labeled in col.4, lines 45-67 and col. 5, lines 1-14) in order to improve the efficiency of the catheter and to provide a better position at a

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selected tissue site. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Adams by adding the second guide wire in order to improve the efficiency of the catheter and to provide a better position at a selected tissue site

***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 5,776,114 to Frantzen

U.S. Pat. No. 6,299,622 to Snow

U.S. Pat. No. 6,093,157 to Chandrasekaran

U.S. Pat. No. 6,602,264 to McGuckin


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X Nguyen whose telephone number is (703) 305-4898.

The examiner can normally be reached on M-F (8-4.30 P.M).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Victor X Nguyen  
Examiner  
Art Unit 3731

Vn 

September 15, 2003

  
MICHAEL J. MILANO  
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